International Journal of Surgery 10 (2012) 587–592

Contents lists available at SciVerse ScienceDirect

International Journal of Surgery

journal homepage: www.theijs.com

Original research

Case matched comparison study of the necrosectomy by retroperitoneal approach with transperitoneal approach for necrotizing pancreatitis in patients with CT severity score of 7 and above

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ARTICLE INFO

Article history:
Received 4 August 2012
Received in revised form
1 September 2012
Accepted 11 September 2012
Available online 27 September 2012

Keywords:
Pancreatic necrosis
Necrosectomy
Transperitoneal vs retroperitoneal technique

ABSTRACT

Background: Minimally invasive necrosectomy through a retroperitoneal approach has shown promising results for the treatment of necrotizing pancreatitis. There is however, little evidence from comparative studies in favor of these techniques over laparotomy.
Aim: To perform a case matched comparison of patients with necrotizing pancreatitis who underwent necrosectomy by the retroperitoneal approach with transperitoneal approach, thus minimizing the risk of confounding and selection bias.
Methods: Between August 2008 and March 2011, 85 patients were admitted with pancreatic necrosis. Each of the 15 patients who underwent necrosectomy by retroperitoneal approach using a small flank incision (RP group) were compared with 15 of those treated with necrosectomy by transperitoneal approach (TP group). These patients were matched for the age (±10 years), status of infection, CT severity score (±2 points), preoperative organ failure and timing for surgery (±7 days).
Results: Postoperative complications occurred in 4 patients (26.6%) in the RP group and 8 (53.3%) in the TP group ($p = 0.248$). Reintervention, was required in 4 patients (26.6%) in the RP group and 7 (46.6%) in the TP group ($p = 0.366$). The median post operative ICU stay was 10 days in the RP group compared to 15 days in the TP group ($p = 0.317$). Median post operative hospital stay was 26 days in the RP group and 32 days in the TP group ($p = 0.431$). The total hospital stay among the survivors was 31 days in the RP group and 40 days in the TP group ($p = 0.285$).
Conclusions: The RP approach for pancreatic necrosectomy through a small flank incision was associated with less post operative morbidity compared to TP approach. The surgical outcomes in terms of post operative new onset organ failure and in hospital mortality were similar in both the groups, but the post op ICU/hospital stay and the total hospital stay was lower in the RP approach group. These results still requires to be confirmed by further randomized studies.

1. Introduction

The spectrum of Acute Pancreatitis ranges from a mild transitory form to a severe necrotizing disease with high mortality. Severe pancreatitis is observed in 15–20% of all cases and is defined as associated with organ failure and or local complications such as necrosis, abscess formation or pseudocysts.[1,2] Observational studies suggest that from its onset, pancreatitis is either edematous or necrotizing.[3] The extent of pancreatic and peripancreatic fat necrosis is probably complete within the first 4 days of the illness.[3] One third of patients with necrosis will have extensive necrosis (over 50% of the gland).[4,5] Necrosum may remain sterile or become infected. Surgical management of patients with infected pancreatic necrosis has undergone remarkable evolution over the last few decades.

However in recent years the mortality and morbidity of this disease has dramatically decreased owing to earlier and more accurate diagnosis and active surgical intervention.[6,7] Anatomical resection was abandoned because of incompleteness of the necrosectomy, needless removal of viable tissue and high mortality.[8] Blunt (non anatomical) debridement of necrotic pancreatic and peripancreatic tissue at laparotomy is the standard method of treatment for patients with infected post inflammatory pancreatic necrosis.[9,10] Most surgical interventions are carried out via the transperitoneal approach,[11–16] scheduled[12,17] or unscheduled reexplorations,[15,18,19] wide spread debridement either with open[12–15]/

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http://dx.doi.org/10.1016/j.ijsu.2012.09.027

close packing[17,20] or continuous lavage[16,21,22] and Pancreatectomy.[23] But these methods require multiple debridement of the necrotic tissue with drainage, a difficult technique that risks intraperitoneal spread of the infection and requires cumbersome postoperative care.[12–16]

Recognition that laparotomy may itself add to morbidity by increasing the post operative organ dysfunction[9] has lead to the recent development of a host of alternative methods for debridement. These alternative methods mostly involve debridement via retroperitoneal, laparoscopic or endoscopic approaches or combination of these.[24] They share the common goal of avoiding laparotomy and collectively are referred to as "Minimally invasive necrosectomy".[25] Minimally invasive necrosectomy through a retroperitoneal approach is gaining popularity for the treatment of necrotizing pancreatitis. The differences include combination with laparotomy,[26,27] wide variation in incision length from 5 cm upto 20 cm[28,29] and routine mobilization of the descending colon.[30]Horvath et al.[31] performed a lumbotomy followed by carbon-dioxide insufflation and retroperitoneoscopic debridement as this allows irrigation of the cavity through the percutaneously placed drain and egress via lumbotomy. Gambiez et al.,[32] in 1998 described the results of necrosectomy for acute pancreatitis through a small left flank incision under visualization using a mediastinoscope. This aims at minimizing surgical stress in an already critically ill patient, thereby potentially reducing the mortality and morbidity. Since then several small series on similar "minimally invasive" retroperitoneal approaches have been published and have shown promising results.[31,33–37] Consequently these techniques are now the preferred method of intervention in several expert centers.

There is however little evidence from comparative studies in favor of these techniques. Selection bias has been thought to be the reason for the favorable outcome of the minimally invasive techniques. The aim of this study is to perform a case matched comparison of patients with necrotizing pancreatitis who underwent necrosectomy by the retroperitoneal approach with transperitoneal approach thus minimizing the risk of confounding and selection bias.

2. Methods & materials

2.1. Patient identification

A total of 85 patients with pancreatic necrosis were admitted to our hospital between August 2008 and March 2011. Out of these 19 patients were treated conservatively and 66 underwent primary pancreatic necrosectomy. For the entire study period the choice of surgical strategy was based on the surgeon's preference. Operation records of these patients were reviewed and patients were grouped according to the type of surgical approach initially selected (Intention to treat principle). A total of 18 patients underwent necrosectomy by retroperitoneal approach during the study period. Out of these 18 patients 15 had CT severity score of more than or equal to 7 and they were included for the study. 48 Patients underwent necrosectomy by transperitoneal approach during the entire study period. All the medical reports and patient charts in these 2 groups were reviewed and the following variables were extracted; date of hospital admission, date of first surgical intervention, bacteriology of peripancreatic and pancreatic necrosis and preoperative organ failure.

2.2. Computed tomography

All preoperative contrast-enhanced computed tomography (CECT) scans were retrieved and reviewed. The following details were analyzed.

1. The CT severity index (CTSI)[38] on the last scan performed before percutaneous drainage (PCD) or surgery was calculated. Patients with CTSI $\geq$ 7 were included in the study.
2. Localization of collection: Collections were classified[39] as: left (left lateral border of the collection $\leq$ 5 cm from the left abdominal wall); intermediate (left lateral border of the collection $>$ 5 cm from the midline); or central (left lateral border of the collection $<$ 5 cm from the midline).
3. Presence of air pockets within the collection – infective necrosis.
4. Accessibility for placement of a percutaneous drain was also assessed.

2.3. Case matching

Out of the 18 patients who underwent necrosectomy by retroperitoneal approach 15 patients had CT severity score of more than or equal to 7 and each of these 15 patients was matched with one patient treated by transperitoneal necrosectomy for all of the following criteria:

(1) Presence or absence of organ failure at any time prior to primary necrosectomy.
(2) Sterile or infected pancreatic necrosis or peripancreatic necrosis as determined by fine-needle aspiration (FNA) and/or intraoperative culture
(3) Timing of surgery: number of days admitted before primary necrosectomy (±7 days, at least 15 days after admission).
(4) Age (±10 years); and
(5) CTSI (±2 points).

These criteria were chosen because it was anticipated that they reflect the most important prognostic factors.

2.4. Data collection of matched cases

The following variables were extracted from the 30 patients' data: Sex; etiology of disease; date of preoperative Percutaneous drainage (PCD); Indication for first surgical intervention; Acute Physiology and Chronic Health Evaluation (APACHE) II score during the 24 h prior to the primary necrosectomy; maximum perioperative white blood cell (WBC) count; indication for reintervention; type of reintervention; complications leading to reintervention; postoperative new-onset organ failure; duration of intensive care (ICU) stay and hospital admission; and date and cause of in-hospital death or date of hospital discharge.

2.5. Surgical strategy

2.5.1. Indication for intervention

Intervention was deemed necessary in cases of proven (FNA) or suspected infection of pancreatic necrosis and/or Peripancreatic necrosis. Infection was suspected when the acute phase of the disease (1–2 weeks) had subsided and there was a sudden onset of spiking fever and an increase in leukocytes in the presence of heterogeneous fluid collections on CT (with or without gas bubbles). Regardless of infection, an intervention was postponed whenever possible in the absence of organ failure or stable organ failure till the third or fourth week after onset of disease, as it is known that during the acute phase the systemic inflammatory response syndrome (SIRS) with MOF is due to sterile inflammation rather than to infection associated with pancreatic and/or peripancreatic necrosis.[40] Moreover, by postponing intervention, the infected collections demarcate and become encapsulated, thereby theoretically optimizing the conditions for surgical intervention.[1,41] FNA was not commonly used in our institution because during the acute phase it had no therapeutic consequences (and we still tried to postpone intervention in cases of a positive bacterial culture) and during the late phase a patient with signs of infection but a negative FNA would still undergo intervention. Moreover, FNA is known to yield false-negative results.[42]

2.5.2. Transperitoneal necrosectomy

Transperitoneal necrosectomy was first described by Beger et al.[43] After a bilateral subcostal or median incision, the lesser sac is entered through the gastro colic omentum. Blunt debridement of all necrotic tissue is performed. Two double-lumen catheters are inserted through separate incisions and positioned in the retroperitoneal space. Opened ligaments are sutured in an attempt to create a closed compartment for local CPL. Planned reintervention is performed only in case if the packing materials were left behind in the lesser sac to control diffuse bleeding and it was planned to come back within 48 h to insert drains for CPL. In case of clinical deterioration, an additional laparotomy for further debridement is performed.

2.5.3. Retroperitoneal approach with CPL

Retroperitoneal drainage is performed under general anesthesia in supine position. The flank is slightly elevated by placing a pillow under the back. A 5 cm incision is made in the left flank. This incision is bluntly and cautiously deepened into the retroperitoneal necrotic space with finger dissection and first the visible necrotic tissue is removed with a forceps under vision. Care should be made not to enter the peritoneum or injure the colon. Then through a blunt dissection using the left kidney as an anatomical landmark along with CT images, the abscess cavity deep in the retroperitoneal space can be drained and the necrotic material removed. Necrotic material is taken for bacterial culture and smear. Finally the retroperitoneal space is inspected with a 0 degree videoscope, introduced through a trocar placed in the edge of the incision. Additional necrosectomy and lavage is performed with a laproscopic forceps and a suction device. Two large bore single lumen drains are

positioned in the cavity and exteriorized through the two edges of the incision. The first drain is placed at the deepest possible point and the second more superficially. The skin is closed, and CPL is applied with at least 10 liters of normal saline through the drainage catheter per day. Catheters are removed if collapse of the cavity is shown on CT and daily production of drainage fluid has decreased to less than 50 ml/24 h. Reintervention is performed only in case of further clinical deterioration.

3. Statistical analysis

All statistical analyses were performed using SPSS version 15 (SPSS, Chicago, IL, USA). Patients who underwent necrosectomy by the retroperitoneal approach were compared with matched patients treated with transperitoneal approach, with mortality as the primary outcome measure. Continuous data were shown as the median and range and were compared with the Wilcoxon rank sum test. For categorical variables, the χ^2 test or Fischer's exact test was used as appropriate. A two-tailed $p < 0.050$ was considered statistically significant.

4. Results

4.1. Baseline characteristics

Preoperative patient demographics are summarized in Table 1. There were 29 men, with a mean age of 41.5 years (31–62 years) in the retroperitoneal group and 41 yrs (30–65 years) in the transperitoneal group (34–75 years). Although 21 patients had been referred by other institutions, all primary necrosectomies were performed in our institution. During the 24 h preoperatively, 15 patients had organ failure, 4 of whom had failure of two or more organ systems. The median APACHE-II score 24 h preoperatively was 11 (range5–21). The median WBC count was 17,600 (range 11,600–21,000). The median CTSI score was 8 (range 7–10). The median time between admission and primary necrosectomy was 31 days (range 17–45 days). The indication for intervention was proven or suspected infection of pancreatic and/or peripancreatic necrosis with evidence of clinical deterioration. All patients had heterogeneous collections containing fluid and necrosis on CECT. Six patients underwent FNA elsewhere before admission which was positive in all cases. Preoperative percutaneous drainage was done in 8 patients, 6 in the RP group and 2 in the TP group. All the patients who underwent PCD had positive bacterial cultures. Infection of the pancreatic necrosis was documented by intraoperative culture in all the patients. Adequate matching was achieved for all criteria. Furthermore, there were no differences between the groups for age, sex, etiology, CTSI, Intra abdominal localization of collection, 24 h preoperative organ failure (single and multiple), preoperative ICU admission, or preoperative WBC count, time between admission and primary necrosectomy and APACHE-II scores.

Table 1
Pre operative characteristics.

Characteristics	RP approach ($n = 15$)	TP approach ($n = 15$)	*P* value
Sex (men)	14	15	0.853
Age (years)[a]	41.5 (31–62)	41 (30–55)	0.885
Etiology			
Alcohol	8	9	0.808
Biliary	6	5	0.763
Other/Unknown	1	1	1.000
CT severity index			
7	5	3	0.480
8–10	10	12	0.670
Intra abdominal localization of collection			
Left	6	4	0.527
Intermediate	3	3	1.000
Central	2	5	0.257
All	4	3	0.705
Accessible for Percutaneous drainage	15	15	1.000
Preoperative percutaneous catheter drainage	6	2	0.157
Organ failure at any time preoperatively	8	8	1.000
Organ failure 24 h preoperatively	7	8	0.796
Multiple organ failure 24 h preoperatively	2	2	1.000
Preoperative ICU admission (days)[b]	10 (2–21)	8 (3–15)	0.637
ICU admission 24 h preoperatively	9	11	0.655
APACHE-II score 24 h preoperatively[b]	12 (5–21)	9 (5–20)	0.513
Time to operation (days)[b]	30 (17–40)	32(18–45)	0.799
Infected necrosis	15	15	1.000

CT: computed tomography; APACHE: acute physiology and chronic health evaluation; ICU: intensive care unit.
[a] Mean and range.
[b] Median and range.

4.2. Complications

In the retroperitoneal approach group, conversion to laparotomy and diversion ileostomy was necessary in one patient who had intraoperative iatrogenic colonic perforation. Four patients in the retroperitoneal group required an additional surgery during the postoperative course, two for post operative complications and two for further necrosectomy.

The details of surgical complications in both the groups are reported in Table 2. There were no significant differences in the incidence of surgical complications in the two groups.

Complications in the retroperitoneal approach group ($n = 4$), were managed as follows:

(1) Bleeding ($n = 1$): Angioembolisation was done, but it failed to control bleeding. So open packing through a laparotomy was done.
(2) Gastrointestinal fistula ($n = 1$): Laparotomy and ileostomy.
(3) Intraoperative iatrogenic colonic perforation ($n = 1$): Laparotomy and repair with ileostomy.
(4) Pancreatic fistula ($n = 1$): Conservative management.

The complications ($n = 8$) in the transperitoneal approach group were managed as follows:

(1) Bleeding ($n = 5$):

Two patients had diffuse bleeding during surgery which was managed by packing and three had bleeding in the post operative period. Of the 3 patients with bleeding in the post operative period, angioembolisation was attempted in two patients, but was successful in one. The patient with failed angioembolisation and the other with bleeding underwent open packing through a relaparotomy.

(2) Gastrointestinal fistula ($n = 1$): Laparotomy and ileostomy.
(3) Colonic necrosis ($n = 1$): Identified intraoperatively and ileostomy done.
(4) Pancreatic fistula ($n = 1$): Conservative management.

Table 2
Post operative surgical complications.

Complications	RP approach	TP approach	*P* value
Bowel perforation	1	0	1.000
Bleeding	1	5	0.102
Colonic necrosis	0	1	1.000
GI fistulas	1	1	1.000
Pancreatic fistula	1	1	1.000
Total	4 (26.6)	8 (53.3)	0.248

4.3. Outcome

Postoperative outcomes are shown in Table 3. Surgical reintervention either for complications or for further necrosectomy was needed in 4 patients of the retroperitoneal approach group and 7 patients in the transperitoneal approach group. Out of the 4 patients in the retroperitoneal approach group, 2 underwent further necrosectomy through a retroperitoneal approach and 2 had laparotomy for post operative complications as bleeding and GI fistula. Of the 7 patients in the transperitoneal approach group 2 underwent relaparotomy for further necrosectomy, 2 for pack removal and 3 for post operative complications (Bleeding-2, GI fistula-1). There were no differences in the total number of surgical reinterventions and other reinterventions as angioembolisation between the two groups. Postoperative new-onset organ failure occurred in 3 patients in the retroperitoneal approach group and 3 in the transperitoneal approach group ($p = 1.000$). The median post operative ICU stay was 10 days in the retroperitoneal group compared to 15 days in the transperitoneal group ($p = 0.317$). The median post operative hospital stay was 26 days in the retroperitoneal group and 32 days in the transperitoneal group ($p = 0.431$). The total hospital stay among the survivors was 31 days in the retroperitoneal group and 40 days in the transperitoneal group ($p = 0.285$). Of the 30 patients, 2 died, one in each group. The cause of death in retroperitoneal group was MOF. This patient had 24 h preoperative APACHE-II score of 21, and CTSI of 8. The cause of death in transperitoneal approach group was bleeding after the primary necrosectomy. The 24 h pre op APACHE II score was 17 and CTSI was 10. This patient underwent relaparotomy and packing. After a median postoperative hospital stay of 25 days (range 15–58 days) the surviving 28 patients were discharged from hospital in good clinical condition.

5. Discussion

Open necrosectomy for infected necrosis carries substantial risks, however, with mortality rates of up to 40%–50% reported even from specialist centers.[9,44–48] A number of less invasive surgical techniques have therefore been developed in an attempt to minimize the excess disturbance of open necrosectomy. Anatomically, its advantage is the minimal trauma to uninvolved tissue, and consequently the comfort for the patients. The nephroscopic technique utilizing a retroperitoneal access route is emerging as the most accepted minimally invasive approach.[49] In this study we used a small left flank incision to approach the retroperitoneum. The advantages of this approach over that of the nephroscopic technique are that, large solid bulky pieces of necrotic material can be removed through the incision, cost effectiveness and decreased need for sophisticated instruments. But this procedure also has certain disadvantages as, need for expertise, more incidence of colonic injury due to blunt dissection and ineffective evacuation of collections located in the transverse mesocolon or the mesentery root.[26]

The timing of the intervention (median 31 days) and percentage of infection at the primary intervention (100%) are among the upper end of data reported in the literature.[50] Outcomes after the retroperitoneal approach are better compared with other reports, which have cited 53% morbidity and 18% mortality rates.[32–36] The morbidity and mortality rates in our study are 26.6% and 6.7% respectively after the retroperitoneal approach. The suggestion that the retroperitoneal approach is associated with increased complication rates[32,33] was not confirmed by our results.

The incidence of complications following the retroperitoneal approach did not differ from that in the transperitoneal group and was similar to those previously reported after laparotomy.[21,44,51–53] Another suggested disadvantage of the retroperitoneal approach is the need for repeated procedures, resulting in a significantly longer postoperative hospital stay compared to that after necrosectomy by laparotomy.[32,33,36] In the current study, however, the number of reinterventions did not differ between groups. This may be explained by the fact that the technique applied in the present study is essentially a semi open approach. The small incision allows removal of large pieces of necrotic tissues far larger than is possible with a purely endoscopic approach.[33,35]

Another disadvantage claimed in this approach is more incidence of visceral injury because of the blunt dissection. This occurred in one patient in our study with RP approach who had intraoperative iatrogenic colonic injury and subsequently this patient underwent laparotomy and diversion ileostomy. A possible explanation toward the improved outcome after the retroperitoneal approach is that the retroperitoneal approach induces less perioperative and postoperative stress than laparotomy because a small (5 cm) incision is used, the peritoneum is left intact, and the peritoneal cavity is not contaminated. Several other authors hypothesized that by minimizing the inflammatory "hit" of necrosectomy the retroperitoneal approach may lessen the risk of postoperative MOF in the already critically ill patient.[31–33,39] In a study by Van Santvoort et al.,[39] the retroperitoneal approach was associated with a significantly less postoperative new-onset organ failure and the morbidity and mortality were 53.3% and 6.7% respectively. Bleeding occurred in 4 patients (26.7%) in the RP group and 1 (6.7%) in the TP group. But in our study there is no difference in the post operative new onset organ failure between the two groups and the morbidity and mortality were 26.6% and 6.7% respectively. Bleeding conversely occurred in only one patient (6.7%) in the RP group and 5 patients (33.3%) in the TP group. The cause of less bleeding after RP approach in our study is due to the application of meticulous technique thereby preserving the vascular strands to avoid bleeding and use of laparoscope for visualization and clipping of any vascular strands and less tissue trauma. The study by Connor et al. also supports the hypothesis of reduced surgical stress using the retroperitoneal approach.[36] In 53% (47/88) of patients, minimally invasive retroperitoneal necrosectomy was performed with 19% mortality compared to 39% mortality after laparotomy ($p = 0.06$). Although no differences in postoperative complication rates were observed, the postoperative APACHE-II score was lower and the postoperative ICU stay shorter in their retroperitoneal group. In our study, although the values are not significant, the RP necrosectomy was associated with less post operative morbidity and shorter post operative ICU/hospital stay and total hospital stay than the transperitoneal approach group. In the current study, the risk of selection bias was minimized by

Table 3
Post operative outcomes.

Outcome	RP approach	TP approach	*P* value
Surgical reintervention:	4	7	0.366
For complications	2	3	0.257
Bleeding	1	2	
GI fistula	1	1	
For further necrosectomy	2	2	
For pack removal	–	2	
Other interventions			
Angioembolisation			
Attempted	1	2	0.564
Successful	0	1	1.000
Postoperative new-onset organ failure	3	3	1.000
Postoperative ICU admissions (days)[a]	10 (7–22)	15 (7–40)	0.317
Postoperative hospital stay (days)[a]	26 (15–32)	32 (15–68)	0.431
Total hospital stays, survivors (days)[a]	31 (20–45)	40 (18–76)	0.285
In-hospital mortality	1 (6.7%)	1 (6.7%)	1.000

[a] Values are the median (range).

matching patients for essentially all criteria known to affect outcome as organ failure,[54,55] infection of necrosis,[1,56] timing of intervention,[1,57] age,[55,58–60] and CTSI score.[1,56,61–63]

We acknowledge that after introduction of the retroperitoneal approach transperitoneal necrosectomy was still performed in some patients. One might therefore argue that there were specific reasons for this (e.g., more extensive necrosis, less accessible collections) and that selection bias was thereby introduced. However, as this was a case-matched design, a control patient was selected from a larger group of patients undergoing laparotomy only if his or her criteria matched those of a patient undergoing the retroperitoneal approach.

In our study patients were comparable for all of the baseline characteristics, including accessibility and intra abdominal distribution of the peripancreatic collections. The fact that transperitoneal necrosectomy was still performed during the study period is primarily explained by the preference of the designated surgeon at that time. Although the sample size is small, the number of patients in this study is at the median of numbers reported in the literature. Nevertheless, the small sample size might have led to a type II statistical error for certain endpoints (e.g., total complications). In the present study, comparability was preferred over power. Although this study represents a higher level of evidence on the subject, the sample size was too small to draw definitive conclusions. Moreover, these results still requires to be confirmed by further randomized studies, especially when considering the improvement in outcome after laparotomy in the recent literature (as low as 6%).[44,64–66]

6. Conclusion

The RP approach for pancreatic necrosectomy through a small flank incision was associated with less post operative morbidity compared to transperitoneal approach. The surgical outcomes in terms of post operative new onset organ failure and in hospital mortality were similar in both the groups, but the post op ICU/hospital stay and the total hospital stay was lower in the RP approach group. These results still requires to be confirmed by further randomized studies.

Funding

None.

Author contribution

Dr.P.Senthil Kumar: Data collection, analysis and writing.
Dr.P.Ravichandran: Study design, analysis.
Dr.S.Jeswanth: Data collection, analysis and writing.

Conflict of interest

None declared.

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